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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,866	09/19/2006	Herve Bercovier	27637U	2826

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
05/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,866	BERCOVIER ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02162010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66-71, 78-85 and 92-94* is/are pending in the application.

4a) Of the above claim(s) *78-80 and 92-94* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-71 and 81-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 02/16/10 in response to the non-final Office Action mailed 09/16/09.

Status of Claims

2) Claims 72-77, 86-91 and 95-100 have been canceled via the amendment filed 02/16/10.

Claims 66-71, 78-82, 84, 85, 92 and 94 have been amended via the amendment filed 02/16/2010.

Claims 66-71, 78-85 and 92-94 are under prosecution.

Claims 66-71 and 81-85 are under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

5) The objection to the specification made in paragraph 6 of the Office Action mailed 09/16/09 is withdrawn in light of Applicants' amendment to the specification.

6) The objection to the claims made in paragraph 19 of the Office Action mailed 09/16/09 is withdrawn in light of Applicants' amendment to the claims.

Objection(s) to Specification

7) The instant specification is objected to for the following reasons:

(a) The first paragraph of the specification newly added via the amendment filed 02/16/10 includes the limitations: 'the entire content of each of which is hereby incorporated by reference in its entirety'. This amendment to the first paragraph of the specification is objected to

under 35 U.S.C. § 132, because it introduces new matter into the disclosure. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The specification, as originally filed, or the transmittal letter, did **not** incorporate by reference the prior applications. For the incorporation by reference to be effective as a proper safeguard against the omission of a portion of a prior application, the incorporation by reference statement must be included in the specification-as-filed, or transmittal letter-as-filed, or in an amendment specifically referred to in an oath or declaration executing the application. An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date. See 35 U.S.C § 132(a).

(b) 37 C.F.R 1.75(d)(1) provides, in part, that 'the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.'

Claims 66, 81 and 82 include the limitations: 'the peptide *optionally* being capable of binding …. and *optionally* being capable of eliciting …. ManLAM binding antibodies' [Emphasis added]. The term 'optionally' allows the peptide not to have the recited capabilities. The amendment thus permits the recited isolated peptide not to have the capacity to bind to ManLAM-binding antibodies and not to have the capacity to elicit production of ManLAM binding antibodies, upon immunization of a subject. However, such an isolated amino acid sequence comprising SEQ ID NO: 1 lacks proper antecedent support in the specification as originally filed. See also paragraph 21 below.

Rejection(s) Moot

8) The provisional rejection of claims 90 and 91 made in paragraph 8 of the Office Action mailed 09/16/09 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36 and 35 of the co-pending application 11630115, is moot in light of Applicants' cancellation of the claims.

9) The rejection of claims 72-77 and 86-91 made in paragraph 12 of the Office Action mailed 09/16/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

10) The rejection of claims 72-76 and 86-90 made in paragraph 14 of the Office Action mailed 09/16/09 under 35 U.S.C. § 102(e)(2) as being anticipated by Pompejus *et al.* (US 7,273,721, filed 6/25/1999) as evidenced by Harlow *et al.* (*In*: *Antibodies: A Laboratory Manual.* Cold Spring Harbor Laboratory, Chapter 5, page 76, 1988), is moot in light of Applicants' cancellation of the claims.

11) The rejection of claims 72, 73, 86, 87 and 89-91 made in paragraph 15 of the Office Action mailed 09/16/09 under 35 U.S.C. § 102(e)(2) as being anticipated by Doucette-Stamm *et al.* (US 6,699,703) as evidenced by Covacci *et al.* (WO 93/18150), is moot in light of Applicants' cancellation of the claims.

Rejection(s) Withdrawn

12) The provisional rejection of claims 66, 82 and the examined claims dependent therefrom made in paragraph 10 of the Office Action mailed 09/16/09 under 35 U.S.C. § 101 as being directed to non-statutory subject matter, is withdrawn in light of Applicants' amendment to claims 66 and 82.

13) The rejection of claims 66, 81 and 82 made in paragraph 12(a) of the Office Action mailed 09/16/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn. A new rejection is set forth below to address the claims as amended.

14) The rejection of claims 66, 81 and 82 made in paragraph 12(b) of the Office Action mailed 09/16/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claims.

15) The rejection of claims 67-71 and 83-85 made in paragraph 12(b) of the Office Action mailed 09/16/09 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

16) The rejection of claims 66-71 and 82-85 made in paragraph 14 of the Office Action mailed 09/16/09 under 35 U.S.C. § 102(e)(2) as being anticipated by Pompejus *et al.* (US 7,273,721, filed 6/25/1999) as evidenced by Harlow *et al.* (*In*: *Antibodies: A Laboratory Manual.*

Cold Spring Harbor Laboratory, Chapter 5, page 76, 1988), is withdrawn in light of Applicants' amendment to the claims and/or the base claim.

17) The rejection of claims 66-71 and 81-85 made in paragraph 15 of the Office Action mailed 09/16/09 under 35 U.S.C. § 102(e)(2) as being anticipated by Doucette-Stamm *et al.* (US 6,699,703) as evidenced by Covacci *et al.* (WO 93/18150), is withdrawn in light of Applicants' amendment to the claims and/or the base claim.

18) The rejection of claim 81 made in paragraph 17 of the Office Action mailed 09/16/09under 35 U.S.C. § 103(a) as being unpatentable over Pompejus *et al.* (US 7,273,721, filed 6/25/1999), is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

19) The provisional rejection of claims 82 and 83 made in paragraph 8 of the Office Action mailed 09/16/09 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36 and 35 of the co-pending application 11630115, is maintained for the reasons set forth therein. Applicants request that this rejection be held in abeyance until an indication of allowable subject matter.

New Rejection(s) Necessitated by Applicants' Amendment

Rejection(s) under 35 U.S.C. § 112, First Paragraph

20) The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

21) Claims 66, 81, 82 and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 66, 81 and 82 include the limitations: 'the peptide *optionally* being capable of binding …. and *optionally* being capable of eliciting …. ManLAM binding antibodies' [Emphasis added]. The term 'optionally' allows the peptide not to have the recited capabilities. The amendment thus permits the recited isolated peptide not to have the capacity to bind to ManLAM-binding antibodies and not to have the capacity to elicit production of ManLAM binding antibodies, upon immunization of a subject. However, such an isolated amino acid sequence comprising SEQ ID NO: 1, a vaccine comprising the same, and a kit for diagnosing mycobacterial infection in a subject comprising the same, lack proper antecedent support in the specification as originally filed. Therefore, the above-identified limitations in the claim(s) and the now claimed scope of the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed, for the new limitation(s), or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (Written Description)

22) Claims 81-85 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 81, as amended, is drawn to a kit for diagnosing mycobacterial infection in a subject, wherein the kit comprises an isolated peptide molecule comprising SEQ ID NO: 1, wherein the peptide is *optionally* being capable of binding to ManLAM-binding antibodies and *optionally* being capable of eliciting, upon immunization in a subject, production of ManLAM binding antibodies. While the limitation 'a subject' encompasses a human and a non-human subject, the generic limitation 'mycobacterial infection' encompasses an infection due to any of a plethora of mycobacterial species, including slow-growing and fast-growing *Mycobacteria*, drug-

resistant *Mycobacteria,* and serious pathogens such as *M. tuberculosis*, *M. leprae*, *M. avium*, *M. paratuberculosis*, *M. kansasii*, *M. xenopi, M. fortuitum, M. szulgai* etc. Claim 82, as amended, is drawn to a vaccine comprising the isolated peptide molecule comprising SEQ ID NO: 1. Claim 82 does not specify against what disease or medical condition is the claimed vaccine meant for. The recited ManLAM binding antibodies encompass anti-ManLAM antibodies, and antibodies which do not bind to non-mannosylated or low mannosylated lipoglycans. See the dependent claims 83-84. The claimed isolated peptide does not bind to the 2H1 anti-glucuronoxylomannan mAb. See the dependent claim 85.

The *Written Description Guidelines* state:

> There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between the structure and function in the art, one skilled in the art will be able to reasonably predict the complete structure of the claimed invention from its function.

The written description requirement can be met by describing the claimed subject matter to a person skilled in the art using sufficiently detailed, relevant identifying characteristics such as functional characteristics, and **correlating** those functional characteristics with a disclosed structure. See *Enzo Biochem v. Gen-Probe,* 323 F.3d 956, 964, 967, 968 (Fed. Cir. 2002). Sufficient description to show possession of a genus may be achieved by means of recitation of a representative number of peptides, defined by amino acid sequences falling within the scope of the genus, or recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Possession may *not* be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. See *University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895.

In the instant application, the claimed isolated peptide comprising SEQ ID NO: 1 encompasses the isolated peptide species having and not having the capability to bind to ManLAM-binding antibodies, and having and not having the capability to elicit, upon immunization in a subject, production of ManLAM binding antibodies, as well as the isolated peptide species having the recited two capabilities. Each peptide species is required to serve as a generic vaccine against an unspecified disease and as a reagent in a kit that diagnoses an infection in a human or non-human subject due to **any species** of *Mycobacteria*. A vaccine 'must by

definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough'. *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). A review of the instant specification indicates the following. In mice experimentally infected with *M. tuberculosis*, one month and three months after the experimental infection, the B11 peptide, SEQ ID NO: 1, binds the significantly elevated IgG antibodies in the infected mice and to ManLAM antibodies. The B11 peptide also binds to high levels of anti-ManLAM antibodies in human patients with *M. tuberculosis* infection. See page 31 and Figures 3 and 4 of the instant specification. The specification states that the anti-B11 antibody titers in BCG-vaccinated individuals were significantly lower than in tuberculosis patients. See page 32 and Figure 4 of the instant specification. Pages 26 and 30 and Figure 2 of the instant specification illustrate that the B11 synthetic peptide when conjugated to KLH via an extra cystiene residue at the N-terminus and administered subcutaneously to mice along with the MPL-TDM adjuvant system induced IgG and IgM Man-LAM binding antibodies. However, Applicants were not in possession of a B11 peptide species, conjugated or non-conjugated, that induces IgG and/or IgM antibodies that bind to ManLAM-binding antibodies and serves as a vaccine, i.e., protects against any generic infection, against any mycobacterial infection, against infection due to ManLAM-containing pathogens, or specifically against *M. tuberculosis* infection, or serves as a diagnostic reagent in a kit capable of diagnosing any non-TB mycobacterial infection. The single isolated peptide sequence species of SEQ ID NO: 1 has not been *correlated* with a generic vaccine function or an anti-mycobacterial vaccine function, and the function of diagnosing an infection due to any species of mycobacteria other than *M. tuberculosis*. A mere statement that the invention includes isolated peptide of SEQ ID NO: 1, optionally having the recited functions, as a generic vaccine or a kit for diagnosing any mycobacterial infection, is insufficient to meet the adequate written description requirement of the claimed invention. With respect to the written description requirement, while 'examples explicitly covering the full scope of the claim language' typically will not be required, there must be sufficient demonstration 'that the patentee possesses the full scope of the [claimed] invention'. *Lizardtech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005). In the instant case, Applicants' specification does not contain adequate written description sufficient to show they had possession of the full scope of the claimed invention at the time the application was filed. A convincing

structure-function relationship has to exist between the structure of the isolated peptide and the generic vaccine (prophylactic) function and the diagnostic function to diagnose any non-TB mycobacterial infections. In the instant application, given the breadth of the required functions, Applicants have not described what domains, contiguous or discontiguous determinants, or conformational or non-conformational epitopes within the claimed peptide are correlated with the above-identified required functions, i.e., the diagnostic and prophylactic (vaccine) abilities. The specification does not describe the claimed embodiments in sufficient detail to convey to a person skilled in the art that Applicants were in possession of the full scope of the claimed invention *at the time of filing*. This is important because at the time of the invention one could not predict the generic or unspecified vaccine functions and the non-TB mycobacterial diagnostic functions of the claimed isolated peptide, SEQ ID NO: 1. The instant claims are viewed as not meeting the written description provision of 35 U.S.C. § 112, first paragraph.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

23) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

24) Claims 66-71 and 81-85 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

(a) Claim 66 is vague and indefinite in the limitation 'A molecule … a peptide represented by an isolated amino acid sequence comprising SEQ ID NO: 1', because it is unclear whether the term 'represented by' is intended to be open or closed claim language. For the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the above-identified limitation with the limitation --An isolated peptide molecule comprising the amino acid sequence of SEQ ID NO: 1--.

(b) Claim 81 is vague and indefinite in the limitation 'an amino acid molecule comprising a peptide represented by an isolated amino acid sequence comprising SEQ ID NO: 1' because it is unclear whether the term 'represented by' is intended to be open or closed claim language. For the purpose of distinctly claiming the subject matter, it is suggested that

Applicants replace the above-identified limitation with the limitation --an isolated peptide comprising the amino acid sequence of SEQ ID NO: 1--.

(c) Claim 82 is vague and indefinite in the limitation 'a molecule comprising a peptide represented by an isolated amino acid sequence comprising SEQ ID NO: 1' because it is unclear whether the term 'represented by' is intended to be open or closed claim language. For the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the above-identified limitation with the limitation --an isolated peptide molecule comprising the amino acid sequence of SEQ ID NO: 1--.

(d) Claims 67-71, which depend directly or indirectly from claim 66, and claims 83-85, which depend directly or indirectly form claim 82, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Claim(s) Objection(s)

25) Claims 66-68, 81 and 82 are objected to for the following reasons:

(a) Claims 66-68, 81 and 82 are objected to for the inconsistent limitations: 'ManLAM-binding antibodies' and 'ManLAM binding antibodies'. It is suggested that Applicants use the former limitation through out the claims.

(b) Claims 66 and 82 are objected to for the comma ',' in line 1 before the limitation 'comprising'.

Remarks

26) Claims 66-71 and 81-85 stand rejected.

27) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

28) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted to the Office's Central Rightfax number 571-273-8300 via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week.

29) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

30) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

May, 2010